

Amendment Under 37 C.F.R. § 1.111
USSN 10/049,456
Attorney Docket Q68463
August 31, 2005

REMARKS

Claims 23-44 are all the claims pending in the application.

The specification has been amended on page 6, line 32 to overcome the objection noted in the last Office Action.

In the last Office Action Claims 33-35, 40 and 42 were objected to and Claims 25, 26, 32 and 37-43 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. Claims 25, 26, 32-35, 37, 42 and 43 have been amended to correct the noted indefiniteness and new Claim 44, which is dependent from Claim 32, has been added. Reconsideration and allowance of the claims are respectfully requested in view of the following remarks.

In the last Office Action Claims 23-25, 32 and 35 were rejected under 35 U.S.C. § 102(b) as being anticipated by Ellard (US Patent No. 5,007,903). Claims 23, 26 and 33-34 were rejected under 35 U.S.C. § 102(b) as being anticipated by Mahurkar (US Patent No. 5,836,921). The presently claimed device is clearly distinguished from the disclosure of each of the references in that the present device is characterized by a “flexible, hollow, elongate catheter” as recited in Claim 23. In rejecting the claims as being anticipated by Ellard, the Examiner stated that Ellard discloses a device which comprises “a flexible, hollow, elongate catheter 28”. However, it is clear that the element 28 in the Ellard device is a hollow needle which is a sharp rigid structure and not a flexible, hollow, elongate catheter as called for in the claim. With respect to Mahurkar it is pointed out that the element 13 of Mahurkar is not a flexible hollow elongate catheter but is a hollow needle. The difference between the flexible, hollow, elongate

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catheter as called for in Claim 23 and the hollow needle disclosed by Ellard and Mahurkar is very significant. The fact that the catheter of the device of the present invention is flexible and elongate is important in that it enables the catheter to follow the internal conformation of an internal cavity of a mammal when the device is used for collection of a fluid sample from such an internal cavity for example, where a fluid sample is to be collected from the uterus of a human female the catheter must follow a curved path as it extends into the cavity. Accordingly, it is absolutely important and essential that the catheter be flexible. In addition, it is equally important the catheter is not a rigid device such as a hollow needle since a hollow needle or a similar device would be likely to puncture the wall of the uterus or other internal cavity (particularly if the rigid device was also sharp as in a needle). With undesirable and possibly severe consequences. Accordingly, it is clear that the flexible, hollow, elongate catheter called for in Claim 23 is not anticipated by or obvious in view of the Ellard or Mahurkar references.

In the last Office Action Claims 37-43 were rejected under 35 U.S.C. § 102(b) as being anticipated by Gravlee (US Patent No. 3,636,940). In rejecting Claim 37 it was stated that Gravlee locates the end of a flexible, hollow, elongate catheter at the opening of an internal cavity but acknowledges that in fact, Gravlee does not disclose a single catheter. The device of Gravlee incorporates separate inlet and outlet tubes which are not disclosed as being flexible. In particular, there is no teaching or disclosure in Gravlee that the “forward portions” of these tubes are flexible. It was also asserted that Gravlee teaches the other two steps recited in Claim 37. However, it is quite clear that the Gravlee device is positioned with forward and extending into the body cavity and the sealing member 23 positioned to seal the entrance to the body cavity

before the source of suction, syringe 33, is operated to provide negative pressure to cause washing solution to pass through the inlet tube into body cavity and then pass through the outlet tube to the collection point. Thus the Gravlee device operates solely by applying negative pressure and it is essential that the body cavity be sealed during operation of the device.

However, the device of the present invention uses both positive pressure to simultaneously pass wash fluid through the hollow catheter as the catheter is moved into the cavity as recited in step (ii) of Claim 37 as well as negative pressure to simultaneously collect a fluid sample through the hollow catheter as the catheter is retracted from the cavity, step (iii) of Claim 37. It was asserted in the Office Action that Gravlee discloses the steps of “simultaneously” passing wash fluid and collecting a fluid sample. However, there is no disclosure or teaching whatsoever in the Gravlee reference of this “simultaneous” operation.

The use of both positive and negative pressure during the performance of the method of the present invention enables the method to be carried out without sealing the body cavity as required by Gravlee. This method gives more efficient washing of the internal cavity since the wash fluid is sprayed through the catheter under positive pressure as the catheter is moved into the cavity. Accordingly, there are clear and significant distinctions between the present method as set forth in Claim 37 and 43 and the method disclosed by Gravlee.

With respect to the rejection of various claims under 35 U.S.C. § 103(a) as being unpatentable over Ellard in view of various other secondary references it is pointed out that none of the secondary references relied on by the Examiner in these rejections discloses or teaches the significant feature which is missing from Ellard, namely the “flexible, hollow and elongate

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catheter” as discussed above. Therefore, it is submitted that none of the secondary references, when combined with Ellard, render the device as claimed in any of Claims 23-36 prima facie obvious.

In view of the foregoing amendments and arguments it is submitted that Claims 23-43 inclusive are in full compliance with requirements of 35 U.S.C. § 112 and are clearly patentable over the prior art applied against the claims in the last Office Action. Therefore, it is respectfully requested that Claim 23-43 inclusive be allowed and the application passed to issue forthwith.

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,



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